2018 Current Fiscal Year Report: Pulmonary-Allergy Drugs Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018
3. Committee or Subcommittee	**3b. GSA Committee No.**
Pulmonary-Allergy Drugs Advisory Committee	1011

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	05/30/2018	05/30/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 1 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 1

Meetings and Dates

Purpose	Start	End
The committee discussed supplemental biologics license application (sBLA) 125526 for mepolizumab for injection, submitted by GlaxoSmithKline for add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts.	07/25/2018	07/25/2018

Number of Committee Meetings Listed: 1

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$4,191.00	$12,031.00
18a(2). Personnel Pmts to Federal Members	$0.00	$0.00
18a(3). Personnel Pmts to Federal Staff	$135,867.00	$131,750.00
18a(4). Personnel Pmts to Non-Member Consultants	$4,191.00	$10,937.00
18b(1). Travel and Per Diem to Non-Federal Members	$5,462.00	$13,417.00
18b(2). Travel and Per Diem to Federal Members	$952.00	$1,914.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$7,394.00	$14,857.00

18c. Other(rents,user charges, graphics, printing, mail, etc.)	$36,567.00	$38,190.00
18d. Total	$194,624.00	$223,096.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in the fields of pulmonary medicine, allergy, clinical immunology, and epidemiology/statistics and are qualified by training and experience to evaluate scientific data. The committee includes one technically qualified member who is identified with consumer interests. The committee may include one non-voting member identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met once during FY-18. On July 25, 2018, the committee discussed supplemental biologics license application (sBLA) 125526 for mepolizumab for injection, submitted by GlaxoSmithKline for add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts. The majority of the committee (16 to 3) voted “no” that the benefit-risk profile is not adequate to support approval of mepolizumab as add-on treatment to inhaled corticosteroid-based maintenance treatment for the reduction of exacerbations in patients with chronic obstructive pulmonary disease (COPD) guided by blood eosinophil counts. In addition, several members again stated the need for additional data, a more clearly defined patient population, and concerns about questionable efficacy. Agency Action: The Agency is still reviewing recommendations made during the meeting. It is expected that the committee will meet two to three times during FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

Members of the committee are drawn from academia research, and/or clinical practice. Their advice lends credibility to FDA's regulatory decisions. The alternate means of obtaining this advice would involve the recruitment of large numbers of scientists on a full-time basis at maximum rates of compensations.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

The committee is not required to do any reporting for FY-18.

Designated Federal Officer

Cindy Chee Designated Federal Officer

Committee Members	Start	End	Occupation	Member Designation
Au, David	04/25/2017	05/31/2020	Professor of Medicine, Univ of Washington	Regular Government Employee (RGE) Member
D'Agostino, Emma	07/19/2018	05/31/2022	Consumer Representative; Advocatem Cystic Fibrosis Foundation	Special Government Employee (SGE) Member
Garibaldi, Brian	06/01/2018	05/31/2022	Assistant Professor of Medicine and Physiology, Johns Hopkins University School of Medicine	Special Government Employee (SGE) Member
Grayson, Mitchell	07/30/2014	05/31/2018	Associate Professor of Pediatrics, Medical College of Wisconsin	Special Government Employee (SGE) Member
Green, Stuart	02/29/2016	10/31/2019	Vice President, Respiratory and Immunology, Merck Research Laboratories	Representative Member
Harkins, Michelle	07/17/2013	05/31/2018	Associate Professor of Medicine, University of New Mexico	Special Government Employee (SGE) Member
Kelso, John	06/01/2018	05/31/2022	Staff Physician, Scripps Clinic	Special Government Employee (SGE) Member
Lederer, David	12/21/2017	05/31/2021	Associate Professor of Medicine and Epidemiology, Columbia University Medical Center	Special Government Employee (SGE) Member
Marshall, Gailen	06/01/2018	05/31/2022	Professor of Medicine, The University of Mississippi Medical Center	Special Government Employee (SGE) Member
May, Susanne	08/27/2017	05/31/2021	Associate Professor of Biostatistics, Univ of Washington	Special Government Employee (SGE) Member
Morrato, Elaine	07/30/2014	05/31/2018	Associate Professor, Colorado School of Public Health	Special Government Employee (SGE) Member
Que, Loretta	12/21/2017	05/31/2021	Associate Professor of Medicine, Duke University Health System	Special Government Employee (SGE) Member
Redlich, Carrie	06/01/2018	05/31/2022	Professor of Medicine, Yale University School of Medicine	Special Government Employee (SGE) Member
Tracy, James	07/17/2013	05/31/2018	Assistant Clinical Professor of Internal Medicine, Creighton University School of Medicine	Special Government Employee (SGE) Member
Wagener, Jeffrey	06/01/2016	05/31/2020	Professor Emeritus, University of Colorado Medical School	Special Government Employee (SGE) Member
Weber, Richard	06/01/2015	05/31/2019	Professor of Medicine, National Jewish Health	Special Government Employee (SGE) Member

Number of Committee Members Listed: 16

Narrative Description

FDA’s strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support

public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Pulmonary-Allergy Drugs Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investgational human drug products for use in the treatment of pulmonary disease and diseases with allergic and/or immunologic mechanisms and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

NA

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Pulmonary-Allergy Drugs Advisory Committee enabled the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed basis rather than on a full time basis. The service of the Committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

30

Number of Recommendations Comments

The committee made 30 recommendations from FY-03 through FY-18. See question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

80%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

10%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve new medical product.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

NA

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

NA